

Case Docket No. NOCAR.007A

Date: September 24, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Otsuki et al.

Appl. No.

10/785,446

Filed

February 23, 2004

For

METHOD OF TREATMENT OF DISEASE USING AN

ADENOSINE A₁ RECEPTOR

ANTAGONIST

Examiner

Unassigned

Group Art Unit:

1614

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

September 24, 2004

(Date)

Sam K. Tahmassebi, Reg. No. 45,151

TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- An Information Disclosure Statement. (X)
- A PTO Form 1449 with forty eight (48) references. (X)
- The Commissioner is hereby authorized to charge any additional fees which may be required, or (X) credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Sam K. Tahmassebi Registration No. 45,151 Attorney of Record Customer No. 20,995 (619) 235-8550

Docket No.: NOCAR.007A Customer No. 20,995

INFORMATION DISCLOSURE STATEMENT

pplicant

Otsuki et al.

App. No.

10/785,446

Filed

: February 23, 2004

For

METHOD OF TREATMENT OF

DISEASE USING AN ADENOSINE A₁

RECEPTOR ANTAGONIST

Examiner

Unassigned

Group Art Unit

1614

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing 48 references. Copies of disclosed U.S. patents and/or publications are not included pursuant to PTO waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for applications filed after June 30, 2003. Copies of other references, if listed, are enclosed.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 24, 2004

By:

Sam K. Tahmassebi

Registration No. 45,151

Attorney of Record

Customer No. 20,995

(619) 235-8550

S:\DOC\$\SKT\SKT-5489.DOC: 092404

FORM	PTO-1449
------	----------

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY.	DOCKET	NO.
NOC	AR 007A	

APPLICATION NO. 10/785,446

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT Otsuki et al.

SE SEVERAL SHEETS IF NECESSARY)

FILING DATE February 23, 2004 GROUP 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1	5,290,782	03/01/94	Suzuki et al.			
	2	5,395,836	03/07/95	Shimada et al.			
	3	5,446,046	08/29/95	Belardinelli et al.			
	4	5,532,368	07/02/96	Kufner-Muhl et al.			
	5	5,599,817	02/04/97	Adamus et al.			
	6	5,631,260	05/20/97	Belardinelli et al.			·
	7	5,641,784	06/24/97	Küfner-Mühl et al.			
	8	5,668,139	09/16/97	Belardinelli et al.			
-	9	5,688,802	11/18/97	Kufner-Muhl et al.			
	10	5,696,124	12/09/97	Kufner-Muhl et al.			
	11	6,187,780	02/13/01	Blech et al.			
	12	6,210,687	04/03/01	Hosokawa et al.			
	13	US 2002/0115687	08/22/02	Beckman et al.			
	14	10/785,446	02/23/04	Otsuki et al.			

FOREIGN PATENT DOCUMENTS								
EXAMINER		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL							YES	NO
	15	WO 01/34604	05/17/01	PCT				
	16	WO 99/55339	11/04/99	PCT				
	17	WO 99/54331	10/28/99	PCT				
	18	WO 94/03456	02/17/94	PCT				

EXAMINER INITIAL	Official population (indepopulation, index, principle and principle)			
	Barrett Richard J., "Realizing the Potential of Adenosine-Receptor-Based Therapeutics," <i>Proc. West. Pharmacol. Soc.</i> (1996);39:61-66	c.		

DATE CONSIDERED

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

⁽ FC	PRM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY, DOCKET NO. NOCAR.007A	APPLICATION NO. 10/785,446
,	INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Otsuki et al.	
	(USE SEVERAL	SHEETS IF NECESSARY)	FILING DATE February 23, 2004	GROUP 1614

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	21	Belardinelli et al.; "1,3 Dipropyl-8-[2-(5,6-Epoxy)Norbornyl]Xanthine, a Potent Specific and Selective A ₁ Adenosine Receptor Antagonist in the Guinea Pig Heart and Brain and in DDT ₁ MF-2 Cells," <i>Journal of Pharmacology and Experimental Theraputics.</i> (1995); 275(3):1167-1176
	22	Bertolet et al., "Differential antagonism of cardiac actions of adenosine by theophylline," Cardiovascular Research. (1996);32:839-845
	23	Broadley, Kenneth J.; "Drugs modulating adenosine receptors as potential therapeutic agents for cardiovascular diseases," Exp. Opin. Ther. Patents. (2000); 10(11):1669-1692
	24	Conlon et al., "Effect of Intravenous Furosemide on Serum Theophylline Concentration," Am. J. Hosp. Pharm. (1981);38:1345-7
-	25	Deckert et al., "Adenosine A ₁ receptors in human hippocampus: inhibition of [³ H]8-cyclopentyl-1,3-dipropylxanthine binding by antagonist drugs," <i>Neuroscience Letters</i> . (1993);150:191-194
	26	Daghfous et al., "Fasting in Ramadan, the asthmatics and sustained-release theophylline," Annals of Saudi Medicine. (1994)
	27	Gellai et al., "CVT-124, a novel adenosine A ₁ receptor antagonist with unique diuretic activity," <i>J. Pharmacol. Exp. Ther.</i> (1998);286(3):1191-6
	28	Giacoia et al., "Diuretics, Hypochloremia, and Outcome in Bronchopulmonary Dysplasia Patients," <i>Dev. Pharmacol. Ther.</i> (1991);4:212-220
	29	Gottlieb, Stephen S.; "Renal Effects of Adenosine A ₁ -Receptor Antagonists in Congestive Heart Failure," <i>Drugs</i> . (2001); 61(10):1387-1393
	30	Gottleib et al.; "BG9719 (CVT-124), an Adenosine A ₁ Receptor Antagonist, Protects Against the Decline in Renal Function Observed with Diuretic Therapy," <i>Circulation</i> . (2002); 105(11):1348-1353
	31	Gottleib et al.; "BG9719 (CVT-124), an A ₁ -Adenosine Receptor Antagonist, Preserves Glomerular Filtration Rate and is an Active Natriuretic in Congestive Heart Failure Patients," <i>Circulation</i> . (1998); 98(17):105
	32	Gottlieb et al., "Effects of BG9719 (CVT-124), an A ₁ –adenosine receptor antagonist, and furosemide on glomerular filtration rate and natriuresis in patients with congestive heart failure," <i>J. Am. Coll. Cardiol.</i> (2000);35(1)56-9
	33	Greenberg et al.; "An Oral Adenosine Antagonist, Preserves Renal Function, Improves Sodium Excretion and is Well Tolerated in Heart Failure Patients," AHA Meeting Orlando, Florida. Poster/Abstract
	34	Ireland et al.; "FK-352 Adenosine A ₁ Antagonist Diuretic Antihypertensive," <i>Drugs of the Future</i> . (1997); 22(4):350-352
	35	Jackson, Edwin K.; "A1 receptor antagonists as diuretic/natriuretic agents," Drugs of the Future.
	36	Jackson et al.; "A ₁ Receptor Blockade Induces Natriuresis with a Favorable Renal Hemodynamic Profile in SHHF/Mcc-fa(cp) Rats Chronically Treated with Salt and Furosemide," <i>Journal of Pharmacology and Experimental Theraputics</i> . (2001); 299(3):978-987
	37	Kobayashi et al.; "Diuretic Effects of KW-3902 (8-(Noradamantan-3-yl)-1,3-dipropylxanthine), a Novel Adenosine A ₁ Receptor Antagonist, in Conscious Dogs," <i>Biol. Pharm. Bull.</i> (1993); 16(12):1231-1235
	38	Lasser, Richad P. "The Treatment of Heart Failure in the 'Intractable' (Refractory) Phase," Advances in Cardiopulmonary Diseases Volume III. Banyai et al. Ed. (1966);3:296-304
	39	Lucas et al.; "Novel Effects of Selective Adenosine Subtype 1(A ₁) Receptor Inhibition on Renal and Pulmonary Function in Heart Failure," Surgical Forum. (2001); 52:95-97
	40	Lucas et al. "Effects of Adenosine Receptor Subtype A ₁ on Ventricular and Renal Function," <i>Journal of Cardiovascular Pharmacology.</i> (2003); 38(4):618-624

EXAMINER	DATE CONSIDERED
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION I IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WIT	

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. NOCAR.007A

APPLICATION NO. 10/785,446

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT Otsuki et al.

FILING DATE February 23, 2004 GROUP 1614

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)		
	41	Lucas et al.; "Cardiorenal Effects of Adenosine Subtype 1(A ₁) Receptor Inhibition in an Experimental Model of Heart Failure," <i>J. American College of Surgeons</i> : (2002); 194(5):603-609		
	Macolić et al., "Pharmacokinetics and interactions of digoxin theophylline and furosemide in diseases with International Journal of Clinical Pharmacology, Therapy and Toxicology (1993);31(1):6-11			
	43	Mazkereth et al., "Effects of theophylline on renal function in premature infants," American Journal of Perinatology (1997);14(1):45-49		
	44	Merzon et al., "Effect of euphylline and lasix on the urea-excretion function of the kidneys in cardiac insufficiency," Sov. Med. (1971);34(5):119-24		
	45	Oberbauer et al.; "Natriuretic effect of adenosine A1-receptor blockade in rats," Nephrology, Dialysis, Transplantation. (1998);13(4):900-3		
	46	Patterson et al.; "Selective A ₁ Adenosine Receptor Antagonism Improves Renal Function in Heart Failure," <i>Circulation</i> . (2000); 102(18):158		
	47	Pfister et al.; "Synthesis and Biological Evaluation of the Enantiomers of the Potent and Selective A ₁ -Adenosine Antagonist 1,3-Dipropyl-8-[2-(5,6-epoxynorbonyl)]-xanthine," <i>J. Med. Chem.</i> (1997); 40(12):1773-1778		
	48	Pietrak A., "Intensive treatment of postoperative acute renal failure using furosemide and euphalline," <i>Pol. Przegl. Chir.</i> (1977);49(10A):1051-3		
	49 Schnackenberg et al.; "An orally active adenosine A ₁ receptor antagonist, FK838, increases renal excretion maintains glomerular filtration rate in furosemide-resistant rats," <i>British Journal of Pharmacology.</i> (2003); 13 1388			
	50	Suzuki et al.; "Adenosine A ₁ Antagonists. 2 Structure-Activity Relationships on Diuretic Activities and Protective Effects against Acute Renal Failure," <i>J. Med. Chem.</i> (1992); 35(16):3066-3075		
	51	Terai et al., "General pharmacology of the new non-xanthine adenosine A ₁ receptor antagonist (+)-(R)-[(E)-3-(2-phenylpyrazolo[1,5-a]pyridin-3-yl)acryloyl]-2-piperidine ethanol," <i>Arzneimittelforschung</i> . (1996);46(2):185-91		
	52	Ticho et al., "Renal Effects of BG9928, an A ₁ Adenosine Receptor Antagonist, in Rats and Nonhuman Primates," <i>Drug Dev. Res.</i> (2003);58:486-492		
	53	Tongia et al., "Infraadditive diuretic efficacy of concurrent aminophylline and frusemide," <i>Indian J. Physiol. Pharmacol.</i> (1993);37(3):244-246		
	54	Watson et al., "Preferences of veterinarians for drugs to treat heart disease in dogs and cats," Aust. Vet. J. 72:401-403		
	55	Welch, William J.; "Adenosine type 1 receptor antagonists in fluid retaining disorders," Expert Opin. Investig. Drugs. (2002); 11(11)1553-1562		
	56	Wilcox et al.; "Natriuretic and Diuretic Actions of a Highly Selective Adenosine A₁ Receptor Antagonist," <i>Journal of the American Society of Nephrology,</i> " (1999); 10(4):714-720		
	57	Wilcox et al.; "Adenosine A ₁ receptor antagonists: A new class of diuretic with blockade of proximal reabsorption and tubuloglomerular feedback," Wiener Klinische Wochenschrift. (1997); 109(12-13):532		
	58	Wolff et al.; "CVT-124, a Novel and Selective A ₁ -Adenosine Antagonist, is a Diuretic in Man with both Proximal and Distal Tubular Sites of Action," <i>Circulation</i> . (1996); 94(8):95		
	59	Wolff et al.; "Renal Effects of BG9719, a Specific A ₁ Adenosine Receptor Antagonist, in Congestive Heart Failure," Drug Development Research. (1998); 45:166-171		
	60	Yao et al.; "The selective adenosine A1 receptor antagonist KW-3902 prevents radiocontrast media-induced nephropathy in rats with chronic nitric oxide deficiency," European Journal of Pharmacology. (2001); 414:99-104		
	61	Yao et al., "Effect of the selective adenosine A ₁ -receptor antagonist KW-3902 on lipopolysaccharide-induced reductions in urine volume and renal blood flow in anesthetized dogs," <i>Jpn. J. Pharmacol.</i> (2000); 84(3):310-5		

EXAMINER	DATE CONSIDERED
	<u> </u>

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

SHEET 4 OF 4

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NOCAR.007A	APPLICATION NO. 10/785,446
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Otsuki et al.	
(USE SEVERAL SHEETS IF NECESSARY)	FILING DATE February 23, 2004	GROUP 1614

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
	62	Zanardo et al., "Methylxanthines Increase Renal Calcium Excretion in Preterm Infants," <i>Biol. Neonate.</i> (1995);68:169-174

S:\DOCS\SKT\SKT-5488.DOC: 092404